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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,660	11/14/2001	Paul D. Johnson	00118.US1	8503

25533 7590 09/24/2003

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EXAMINER

SAEED, KAMAL A

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,660	JOHNSON ET AL.	
	Examiner	Art Unit	
	Kamal A Saeed	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 28-33,35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-27,34 and 37-42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 1 – 42 are pending in this application. Claims 28-33, 35 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions

In response to Office Action mailed on February 28, 2003, Applicants requested the list of the different patentably distinct compounds of Formula I. Therefore, Invention Group I of the previous Office Action has been divided into several Groups for clarification purposes.

The Markush group set forth in the claim1 includes both independent and distinct inventions, and patentable distinct compounds within each invention. However, this application discloses and claims a plurality of patentable distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentable distinct compounds, also far too numerous to list individually. **For these reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121.** The following are some of the patentably distinct groups:

- I. Claims 1-27, 34, and 37-42, are drawn to compounds and compositions of formula I, wherein: X is O or S(=O)_n; Y is NHC(=W)R¹; W is O or S; R¹ - R⁹ are as defined except that they don't represent a heterocyclic group; m and n are as defined; and G, E and Q are as defined in claim 1, variously classified in classes 548, 514 and several subclasses.
- II. Claims 1-27, 34, and 37-42, are drawn to compounds and compositions of formula I, wherein: X is NR³; Y is NHC(=W)R¹; W is O or S; R¹ - R⁹ are as defined except that they don't represent a heterocyclic group; m and n each

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represent 1; G, E and Q are as defined in claim 1, variously classified in classes 546, 514 and several subclasses.

- III. Claims 1-27, 34, and 37-42, are drawn to compounds and compositions of formula I, wherein: X is NR^3 ; Y is $\text{NHC}(=\text{W})\text{R}^1$; W is O or S; $\text{R}^1 - \text{R}^9$ are as defined except that they don't represent a heterocyclic group; ; m and n each represent 2; G, E and Q are as defined in claim 1, variously classified in classes 540, 514 and several subclasses.
- IV. Claims 1-27, 34, and 37-42, are drawn to compounds and compositions of formula I, wherein: X is NR^3 ; Y is O-het or S-het; W is O or S; $\text{R}^1 - \text{R}^9$ are as defined except that they don't represent a heterocyclic group; ; m and n each represent 2; G, E and Q are as defined in claim 1, variously classified in classes 540, 514 and several subclasses.
- V. Claims 1-27, 34, and 37-42, are drawn to compounds and compositions of formula I, wherein: X is O or $\text{S}(=\text{O})(=\text{NR}^4)$; Y is $\text{NHC}(=\text{W})\text{R}^1$; W is O or S; $\text{R}^1 - \text{R}^9$ are as defined except that they don't represent a heterocyclic group; ; m and n each represent 0-2; G, E and Q are as defined in claim 1, variously classified in classes 540, 514 and several subclasses.

Where an election of any one of Groups is made, an election of a single compound is further required including an exact definition of each substitution on the base molecule (Formula (I)), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R^1 , wherein R^1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent f

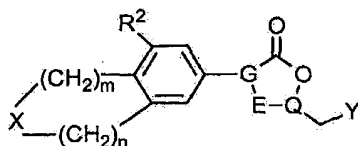
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R1, for example OH or aryl and each subsequent variable position. In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compound are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

Status of the Claims

The scope of the elected invention, as described in the Office Action mailed on February 28, 2003 as follows:

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Compounds of formula I,

I

wherein:

X is NR^3 ; **G** is N; **E** is CH_2 ; **Q** is CH; **O** is O; **W** is O or S; **Y** is as defined

R¹ is H, C₁₋₈ alkyl, C₃₋₆ cycloalkyl, OC₁₋₄ alkyl, SC₁₋₄ alkyl, NH₂, NHC₁₋₆ alkyl or N(C₁₋₆ alkyl)₂;

R² is H, halo or C₁₋₄ alkyl;

R³-**R**⁹ are as defined with the exception that they don't represent a heterocyclic group;

m is 2; and **n** is 2.

As a result of the election and the corresponding generic concept identified, the remaining subject matter of claims 1-27, 34 and 37-42 and claims 28-33, 35 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. As a result of the election and the corresponding compounds identified supra, the remaining subject matter of claims 1-27, 34 and 37-42 as stated previously are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions.

Applicants Arguments

Applicants argue that the examiner recasting of the claims to the scope of the elected invention improperly limits the scope of Applicants claims. However, the scope of the elected invention does not improperly limit the scope of Applicants claims. The compounds, which are withdrawn from consideration as being non elected subject matter, differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds

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contain varying functional groups which differ from those of the elected invention such tetrazine, triazine, diazine, morpholine, thiazine, oxazole, thiazole, triazole, group etc. This recognized chemical diversity of the functional groups can be seen by various classification of these functional groups in the US classification system i.e. class 544 subclass 106+ (morpholine), class 546 subclass 184+ (piperidine), class 548 subclass 400+ (indole) etc. Therefore, the compounds, which are withdrawn from consideration as being for non elected subject matter, differ materially in structure and composition and have been restricted properly as a reference, which anticipated, but the elected subject matter would not even render obvious the non-elected subject matter.

Applicant's claim involves more than one independent or distinct invention . Under 35 U.S.C. 121, the claims may be restricted and the examination limited to the restricted invention. Accordingly, restriction as has been presented in this application is proper. The requirement to restrict is repeated and made Final.

Objections

Claims 1-27, 34, and 37-42 are objected to for containing non-elected subject matter. Claims 1-27, 34, and 37-42, drawn solely to the elected invention as identified supra, would appear allowable over the prior art of record.

Therefore **THIS ACTION IS MADE FINAL** . Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal Saeed whose telephone number is (703) 308-4592. The examiner can normally be reached on Monday-Friday from 8:00 AM – 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308 4537. The unofficial fax phone for this group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy

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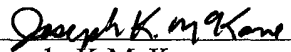
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published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG
89.

Any inquiry of a general nature or relating to the status of this application should be
directed to the Group receptionist, whose telephone number is (703) 308-2286.

Kamal Saeed, Ph.D
September 18, 2003



Joseph K McKane,
Supervisory Patent Examiner
Art Unit 1626, Group 1626
Technology Center 1